UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/597,851	08/09/2006	Karlheinz Bortlik	112701-746	7063

29157 7590 07/26/2007

BELL, BOYD & LLOYD LLP
P.O. Box 1135
CHICAGO, IL 60690

EXAMINER
CHEN, CATHERYNE

ART UNIT	PAPER NUMBER
1655	

NOTIFICATION DATE	DELIVERY MODE
07/26/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATENTS@BELLBOYD.COM

Office Action Summary	Application No.	Applicant(s)	
	10/597,851	BORTLIK ET AL.	
	Examiner	Art Unit	
	Catheryne Chen	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 May 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6-9 and 11-26* is/are pending in the application.

4a) Of the above claim(s) *17-21* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6-9,11-16 and 22-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *09 August 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *Dec. 12, 2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Currently, Claims 1-4, 6-9, 11-26 are pending. Claims 1-4, 6-9, 11-16, 22-26 are examined on the merits. Claims 5 and 10 are canceled.

Election/Restrictions

Applicant's election without traverse of Group I (Claims 1-16, 22-24) in the reply filed on May 9, 2007 is acknowledged.

Claims 17-21 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected group, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on May 9, 2007.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 23 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treatment of skin, does not reasonably provide enablement for preventing skin dryness. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Undue experimentation would be required to practice the invention as claimed due to the quantity of experimentation necessary; limited amount of guidance and limited number of working examples in the specification; nature of the invention; state of the prior art; relative skill level of those in the art; predictability or unpredictability in the

art; and the breadth of the claims. In re Wands, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

Applicant's claims are broadly drawn to a composition that is able to prevent sry skin. In order to be enabled for prevention of a condition, applicant must demonstrate that the invention is able to prevent the condition each and every instance of that condition. Applicant's specification does not set forth any evidence that the claimed product is able to prevent dry skin for all potential causes of dry skin. In addition, the art teaches dry skin prevention is not accepted as possible because many risk factors such as environment, diet, age, race and family history cannot be controlled (see http://www.uihealthcare.com/topics/skinhealth/winterskin.html). Because applicant's specification does not show prevention of dry skin and the art acknowledges that prevention is not currently possible, a person of ordinary skill in the art would be forced to experiment unduly in order to determine if applicant's invention actually functions as claimed. Therefore, the claims are not considered enabled for the prevention of dry skin.

Claims 24 and 26 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating cancer, does not reasonably provide enablement for preventing cancer. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Undue experimentation would be required to practice the invention as claimed due to the quantity of experimentation necessary; limited amount of guidance and

limited number of working examples in the specification; nature of the invention; state of the prior art; relative skill level of those in the art; predictability or unpredictability in the art; and the breadth of the claims. In re Wands, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

Applicant's claims are broadly drawn to a composition that is able to prevent cancer. In order to be enabled for prevention of a condition, applicant must demonstrate that the invention is able to prevent the condition each and every instance of that condition. Applicant's specification does not set forth any evidence that the claimed product is able to prevent cancer for all potential causes of cancer. In addition, the art teaches some cancer prevention is not accepted as possible because many risk factors such as environment, social behavior, age, race and family history cannot be controlled (see http://www.cancer.gov/cancertopics/wyntk/overview/page4). Because applicant's specification does not show prevention of cancer and the art acknowledges that prevention is not currently possible, a person of ordinary skill in the art would be forced to experiment unduly in order to determine if applicant's invention actually functions as claimed. Therefore, the claims are not considered enabled for the prevention of cancer.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4, 6-9, 11-16, 22-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In Claims 1-4, 6-9, 11-16, 22, 23, 24, 26, what is meant by "enriched?"

In Claim 16, what is "10.sup.-10%?"

In Claim 23, what is meant by "sensible" or "reactive" skin?

Claims 16 and 25 recite the limitation "the content." There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-4, 6, 8, 9, 11-15, 22, 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Hartal et al. (US 5965183).

Hartal et al. teaches lycopene concentrates for use in food coloring, nutraceuticals, pharmaceuticals, and cosmetic formulations, lyopenes from vegetable extracts (column 1, lines 7-9, 16-19), food-compatible liquid, pharmaceutically-

acceptable liquid, cosmetically-acceptable liquid (column 6, lines 26-42), oleoresin contains about 2-10% lycopene (Claim 17).

Hartal et al. does not specifically teach using lycopene to treat skin. However, the method of treating skin is considered to inherently teach the claimed method because both the reference and the claimed invention are administering the same composition to the same patient. The patient is the same because every person has skin. Thus, on the administration of lycopene to any patient, a treatment of skin would have had to occur if applicant's invention function as claimed.

Claims 1-4, 6, 8, 9, 11-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Rodriguez et al. (US 6329557 B1).

Rodriguez et al. teaches carotenoids from plants, fish, crustaceans, birds, algae, and bacteria, to isolate beta-carotene, lutein and zeaxanthin, capsanthin, canthaxanthin, and astaxanthin (column 1, lines 9-20), where the concentration of carotenoids in the dispersion is between about 0.1 to 15 grams per kilogram of the extract (Claim 17), for use in pigmenting formulations as animal feed (column 1, lines 26-27).

Claims 1-4, 6, 8, 9, 11-16, 22, 24-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Haigh (US 5310554).

Haigh teaches composition of purified natural beta-carotenes and methods for purification from plants. The beta-carotene preparations are enriched in the 9-cis isomer. Purified beta-carotenes are useful as dietary vitamin A supplementation, as

pharmaceuticals, as anti-oxidants in therapeutic and preventative applications (column 1, lines 5-14). Carotenes can be extracted from vegetables, fruits, algae. Beta-carotene can prevent or reduce the risk of heart disease and stroke and cancers, such as breast, lung, colon, prostate, and cervix (column 1, lines 28-29, 33-36). The composition may comprise carotenoids, cis-beta carotene isomers about 3% or less. The high purity natural beta-carotene preparations may be combined with pharmaceutically acceptable carriers, preservatives, vitamin supplements or other medicinal agents in a variety of formulations and dosages for administration to humans or other animals. The formulation are typically a capsule, liquid, tablet or powder (column 2,lines 31-51). For solid compositions, the compounds can be with conventional carriers, glucose, sucrose, and may contain about 10-100% active ingredients (column 6, lines 24-36). As a dietary supplement, 9-cis beta-carotene may be supplied as an oil, suspended in a capsule, beadlet, or incorporated directly into foodstuffs (column 6, lines 48-52). The pharmaceutical compositions are for oral, local, topical or parenteral administration for prophylactic or therapeutic treatment (column 8, lines 54-59).

Haigh does not specifically teach using carotenoids to treat skin. However, the method of treating skin is considered to inherently teach the claimed method because both the reference and the claimed invention are administering the same composition to the same patient. The patient is the same because every person has skin. Thus, on the administration of carotenoids to any patient, a treatment of skin would have had to occur if applicant's invention function as claimed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-4, 6-9, 11-16, 23-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haigh (US 5310554).

Haigh teaches composition of purified natural beta-carotenes and methods for purification from plants. The beta-carotene preparations are enriched in the 9-cis isomer. Purified beta-carotenes are useful as dietary vitamin A supplementation, as pharmaceuticals, as anti-oxidants in therapeutic and preventative applications (column 1, lines 5-14). Carotenes can be extracted from vegetables, fruits, algae. Beta-carotene can prevent or reduce the risk of heart disease and stroke and cancers, such as breast, lung, colon, prostate, and cervix (column 1, lines 28-29, 33-36). The composition may comprise carotenoids, cis-beta carotene isomers about 3% or less.

The high purity natural beta-carotene preparations may be combined with pharmaceutically acceptable carriers, preservatives, vitamin supplements or other medicinal agents in a variety of formulations and dosages for administration to humans or other animals. The formulation are typically a capsule, liquid, tablet or powder (column 2,lines 31-51). For solid compositions, the compounds can be with conventional carriers, glucose, sucrose, and may contain about 10-100% active ingredients (column 6, lines 24-36). As a dietary supplement, 9-cis beta-carotene may be supplied as an oil, suspended in a capsule, beadlet, or incorporated directly into foodstuffs (column 6, lines 48-52). The pharmaceutical compositions are for oral, local, topical or parenteral administration for prophylactic or therapeutic treatment (column 8, lines 54-59). However, it does not teach the claimed concentrations.

The reference also does not specifically teach adding the ingredients in the amounts claimed by applicant. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Thus, optimization of general conditions is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results. Thus, absent some demonstration of

unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

Haign teaches that oleoresin composition can be used topically. Thus, an artisan of ordinary skill would reasonably expect that oleoresin composition could be used as the types of method to prevent or treat "sensible, dry or reactive" skins. This reasonable expectation of success would motivate the artisan to use oleoresin composition in a liquid composition to treat skin in the reference composition. Thus, using oleoresin composition is considered an obvious modification of the reference.

Conclusion

No claim is allowed.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catheryne Chen whose telephone number is 571-272-9947. The examiner can normally be reached on Monday to Friday, 9-5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Catheryne Chen
Patent Examiner
Art Unit 1655

/Susan Hoffman/
Primary Examiner, Art Unit 1655